ATTACHMENT B

NIH/NIDCR CONSENSUS DEVELOPMENT CONFERENCE (CDC) ON CARIES

SUBSECTION ON SALIVA AS A RISK FACTOR IN CARIES

DATA EXTRACTION FORM

Reviewer ID (please circle): FO CL Other (please indicate initials):_____

Year of Publication:_____ Article Unique Identifier:_____

Authors' Names (in the Evidence Tables list the name of first author followed by et al.):_____
_____

Journal:_____ Volume & Pages:_____

Article Initially Screened (by CL) via Abstract/Title (please circle): Yes No [Stop if No]

Article Meets Inclusion Criteria (please circle): Yes No [Stop if No]
Inclusion Criteria: Human subjects; Caries status of subjects indicated; Articles in English; Year 1986 or later

Source of Data Extraction (please circle): Used Article Used Abstract

STUDY DESCRIPTION

Article Focus (please circle): Etiology Diagnosis Outcomes/Prognosis Treatment/Therapy Prevention
Note: Most articles will be classified as Etiology and/or Diagnosis

Article Type (please circle): Original Report (comparative study) Original Report (non-comparative study)
Abstract/Proceedings Review/Monograph Letter to Editor/Editorial

Study Design/Level or Grade of Evidence (AHRQ scale):

Level (please circle):	General Description	Study Design (please circle):
I	(Intervention Studies, complete randomization)	Randomized Controlled Clinical Trial (RCT)
II-1	(Intervention Studies, partial or no randomization)	Non-Randomized Controlled Clinical Trial (CCT)
II-2	(Analytic/Longitudinal, with controls)	Cohort (longitudinal) Study; Case-Control Study
II-3	(Multiple cross-sectional samplings)	Multiple Time Series Study
III	(Descriptive Studies-in vivo or in situ)	Descriptive Cross-sectional Characterization, with information on caries status of subjects & without comparison group Case Report/Series; Report of Expert Committee; Opinions of Respected Authorities; Clinical Experience Studies using artificial intraoral appliances containing teeth or tooth components, with information on caries status of subjects & comparison group In vitro-formed pellicle , with information on caries status of subjects & comparison group

IV (Descriptive Studies-Laboratory (in vitro) or Animal) Descriptive Characterization, without information on caries status of subjects & comparison group
Studies using artificial intraoral appliances containing teeth or tooth components, without information on caries status of subjects & comparison group
In vitro-formed pellicle, without information on caries status of subjects & comparison group
Exclusively Biochemical/Biophysical Study
Exclusively Cell/Tissue Culture Study
Animal Study; Comparative Zoology Study
Other

Notes: 1) Case-Control studies are those which start with the identification of persons with a disease of interest (i.e., caries) and a control or comparison group without the disease; the relationship of an attribute to the disease is examined by comparing diseased and non-diseased persons with regard to the frequency or levels of the attribute in each group

2) Cohort studies are those in which subsets of a defined population are identified; these groups may or may not be exposed to factors hypothesized to influence the probability of the occurrence of a particular disease or other outcome; cohorts are defined populations which, as a whole, are followed in an attempt to determine distinguishing subgroup characteristics

3) Studies of Grade IV are generally excluded from analysis; to be included, descriptive studies should meet a minimum quality standard based upon the criteria for evaluation (e.g., presence of a comparison group, control for confounding factors, internally valid, etc.)

STUDY SUBJECTS CHARACTERISTICS/DEMOGRAPHIC INFORMATION

Source of Sample and Country:_____Race/Ethnicity/National Origin:_____
_____

Age(s) of Sample(s): Mean Age (±SD):_____ Age Range:_____ No Data

Number of Subjects by Gender: Females:_____ Males:_____ Total:_____ No Data

Number of Subjects in each Group: High Caries Risk/Response:_____ Low Caries Risk/Response:_____
Comment: "High" and "Low" defined as_____
_____

Other Demographic Information:_____

STUDY CHARACTERISTICS

Funding Source (please circle): Government Industry/Pharmaceutical Private Unfunded No Data

Study Setting (please circle): University Private Office Hospital Nursing Home/Assisted Living
Community/Government Clinic Community Dwelling Other No Data

Number of Study Arms:_____ Multicenter (please circle): Yes No (if Yes, # centers:_____)

Length of the Study:_____

Sampling Method (please indicate how/why subjects were chosen): (circle here if Unspecified/No Data)

_____

_____

Response Rate (please indicate the number or percent of subjects contacted who consented to participate in the study):_____ (circle here if Unspecified/No Data)

Training of Examiners (please indicate the number of examiners and if/how they were trained for the study):_____

_____

Reliability of Examiners (please indicate if examiner reliability was described):

Intra-examiner reliability of caries assessment was measured (please circle): Yes No Unclear
(if Yes, indicate: Kappa value_____ or Percent agreement_____ or Other_____)

Inter-examiner reliability of caries assessment was measured (please circle): Yes No Unclear
(if Yes, indicate: Kappa value_____ or Percent agreement_____ or Other_____)

Intra-examiner reliability of saliva assessment was measured (please circle): Yes No Unclear
(if Yes, indicate: Kappa value_____ or Percent agreement_____ or Other_____)

Inter-examiner reliability of saliva assessment was measured (please circle): Yes No Unclear
(if Yes, indicate: Kappa value_____ or Percent agreement_____ or Other_____)

Other Relevant Data (e.g., questionnaires, other demographic data, quality of data); (please list):_____

_____

Controls for Confounding Factors (please circle):Yes No (If Yes, please describe):_____

_____

Blinding of Examiners (please circle): Yes No

Blinding of Patients (please circle): Yes No

Number of Lost Subjects (please indicate number of subjects lost and reasons e.g., withdrawals, non-responders, other):_____

Statistics/Method of Data Analysis (please indicate):_____

<u>CARIES STATUS ASSESSMENT</u>

Criteria for Detection and Monitoring of Dental Caries (please indicate):

Notes: 1) These generally include evidence of advancement from early caries, to cavitation, to tooth loss; early vs. advanced, NIDCR criteria, WHO criteria, other criteria

2) If Unknown/No Data, indicate "ND" next to appropriate entry below

Tooth/Dentition Type (please circle all that apply): Primary Permanent Mixed
Exogenous Tooth Block Other_____

Caries Scoring Method (please circle all that apply): DMFS DMFT dmfs dmft Missing CI
Other_____

Caries Detection Method (please circle all that apply): Clinical Examination Radiographs Laboratory
Other_____

Caries Process Described (please circle all that apply): Cavitated Lesion Demineralization
Remineralization Other_____

Caries Extent (please circle all that apply): Into Enamel Into Dentin Into Cementum

Caries Location (please circle all that apply): Crown Root Exogenous Tooth Block

Caries Risk Assessment Indicators Used (please indicate):

Notes: 1) These generally include both subjective and objective measures

2) If Unknown/No Data, indicate "ND" next to appropriate entry below

Subjective (please circle all that apply):
Subject Self-reported Symptoms
Non-validated Questionnaire (incl. oral habits, SES, etc.)
Other_____

Objective (please circle all that apply):
Clinical Judgment Based on Dental Examination (clinical and/or radiographic)
Validated Questionnaire (incl. oral habits, SES, etc.)
Salivary Test (incl. flow rate, buffer capacity, pH, Dentobuff Strip®, etc.)
Microbiology (incl. microbial counts, mutans streptococci, Dentocult SM®, lactobaccilli, Dentocult LB®, etc.)
Other_____

Risk Category Defined for Test/Experimental Group(s) (please circle): No/Low Moderate High
(aka: Caries-resistant; Caries-susceptible; Caries-free; Caries-active)

Risk Category Defined for Comparison/Control Group(s) (please circle): No/Low Moderate High
(aka: Caries-resistant; Caries-susceptible; Caries-free; Caries-active)

Clinical Decision Making for each Group of Caries Risk Status (please indicate):

Notes: 1) These generally describe the kind of preventive or therapeutic intervention applied to each test or control group following the assessment of risk; not all studies will report this

2) If Unknown/No Data, indicate "ND" next to appropriate entry below

For No/Low Risk Test/Experimental Group(s) (please circle):
No Change in Preventive Regimen
Basic/Simple Preventive Regimen
Intensive Preventive Regimen

For Moderate Risk Test/Experimental Group(s) (please circle):
No Change in Preventive Regimen
Basic/Simple Preventive Regimen
Intensive Preventive Regimen

For High Risk Test/Experimental Group(s) (please circle):
No Change in Preventive Regimen
Basic/Simple Preventive Regimen
Intensive Preventive Regimen

For No/Low Risk Comparison/Control Group(s) (please circle):
No Change in Preventive Regimen
Basic/Simple Preventive Regimen
Intensive Preventive Regimen

For Moderate Risk Comparison/Control Group(s) (please circle):
No Change in Preventive Regimen
Basic/Simple Preventive Regimen
Intensive Preventive Regimen

For High Risk Comparison/Control Group(s) (please circle):
No Change in Preventive Regimen
Basic/Simple Preventive Regimen
Intensive Preventive Regimen

SALIVA STATUS ASSESSMENT

Description of Risk for Caries as Related to Saliva (please circle):

Article Describes Evidence for a Protective Effect of Saliva against Caries (i.e., host defense)

Article Describes Evidence for No Effect of Saliva against Caries

Article Describes Evidence for a Caries-promoting Effect of Saliva

Description of Salivary Physiology (please circle all that apply)

Normal Physiology Reduced Quantity/Hypofunction/Xerostomia Altered Quality
Increased Quantity/Hyperfunction Unspecified/No Data

Reason for Reduced Quantity and/or Altered Quality of Saliva (please indicate):

Notes: 1) These generally describe any number of changes in saliva resulting from systemic diseases, drugs, environmental factors and other subject-specific influences

2) If Unknown/No Data, indicate "ND" next to appropriate entry below

Disease-Related (please circle all that apply):

Sjogren's Syndromes
1°=KCS and xerostomia w/o other major CT disease
2°= " or " with " " " " (e.g. RA, SLE, Primary Biliary Cirrhosis, Scleroderma)
Crohn's Disease
Radiotherapy affecting Salivary Glands
Chemotherapy affecting Salivary Glands
Surgery affecting Salivary Glands
Agenesis/Hypogenesis of Salivary Glands
Other Exocrinopathy
Anorexia Nervosa
Bulimia Nervosa
Chronic Malnutrition
Other_____

Medication/Drug-Related (please circle all that apply):

Anti-hypertensive agents
Anti-psychotic/psychotropic agents
Anti-secretogogues
Other_____

Other Subject-Related (please circle all that apply):

Stress
Smoking
Diet
Age
Gender
Ethnicity
Other_____

Form of Saliva Evaluated (please circle): In Solution/Free Surface-adsorbed/Bound (i.e., pellicle)

Source of Saliva Evaluated (please circle):

Whole Saliva (also circle whether: *Stimulated or Unstimulated)
* Please also note if stimulation is masticatory or gustatory.

Parotid Gland Secretion (also circle whether: Stimulated or Unstimulated)

Submandibular/Sublingual Gland Secretion (also circle whether: Stimulated or Unstimulated)

Minor Gland Secretion (also circle whether: Stimulated or Unstimulated)

Type of Salivary Function Evaluated (please circle):

General Protective/Lubrication

Microbial Agglutination/Binding and Clearance

Microbial Colonization/Adherence to Tooth Surfaces

Microbial Growth-promoting or inhibiting/Microbial Nutrition (incl. enzymatic activities)

Microbicidal/Microbistatic Effects

Control of Demineralization/Remineralization

Inter-individual Transmissibility of Microbiota

Unspecified

Individual Salivary Characteristics Evaluated (please indicate):

Notes: 1) These generally describe any number of physical and chemical aspects of saliva

2) If Unknown/No Data, indicate "ND" next to appropriate entry below

Physical Aspects(please circle all that apply):

Flow Rate/Amount
Salivary Film Velocity
Food/Nutrient/Microbial Clearance Rate
Site-specific Presence
Other_____

Chemical Aspects-Electrolytes/Small Molecules:
(please circle all that apply)

Buffer Capacity
pH
Simple Carbohydrates
Electrolytes
Trace Elements
Calcium level
Phosphate level
Sodium level
Chloride level
Carbonate level
Bicarbonate level
Urea level
Fluoride level
Copper level
Zinc level
Magnesium level
Manganese level
Iron level
Selenium level
Other_____

Chemical Aspects-Macromolecules
(please circle all that apply)

Macromolecules
Proteins/Glycoproteins/Phosphoproteins
Lipids/Glycolipids/Phospholipids/Lipoproteins
Complex Carbohydrates
Enzymes
Ionophores
Immune components
Non-immune components
Acidic proteins
Basic proteins
Amylase
Proline-rich proteins (PRPs)

Mucins/MG1/MG2
Statherins
Histatins
Cystatins
Peroxidase
Lactoferrin/Transferrin
Lysozyme
Immunoglobulins (IgA, IgG, IgM)
Other_____

Relationship Evaluated Between Individual Salivary Characteristics and Which of the Following (please indicate):

In Vivo Caries (e.g., DMFS)/Demineralization/Remineralization in subjects	[Include]
In Situ/Ex Vivo Caries (e.g., DMFS)/Demineralization/Remineralization	[Exclude if there is no comparison group]
In Vitro Caries (e.g., DMFS)/Demineralization/Remineralization	[Exclude]
Animal Caries (e.g., DMFS)/Demineralization/Remineralization	[Exclude]

STUDY FINDINGS/OUTCOMES

Main Response Variable (e.g., caries prevalence; caries incidence/increment over time, etc. expressed as DMFS, DFS, DS or other variable):_____

Findings (e.g., statistical measures of central tendency and association: means, SD, SEM, odds ratios, risk ratios, likelihood ratios, sensitivity, specificity, or others; incl. 95% confidence intervals if possible):_____
_____
_____
_____
_____
_____
_____

Type of Association (please indicate): Linear, Positive Linear, Negative Threshold
Other non-linear Uncertain

Description of Intra- or Intersubject Variations in Salivary Characteristics (please describe):_____
_____
_____
_____

Applicability of Findings (please indicate): To Individual Subjects To Population Groups Uncertain

AUTHORS' CONCLUSIONS

Please indicate the conclusion(s) reported by the authors:_____
_____
_____
_____
_____

COMMENTS BY EXTRACTOR

Please indicate any further comments, notes or observations:_____
_____
_____
_____
_____

Do investigators need to be contacted for more information? (please circle): Yes No (if Yes, what data should be obtained?)_____
_____